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10/713,970	11/14/2003	Roland Contreras	17106	5158

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EXAMINER	
GEBREYESUS, KAGNEW H	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,970	CONTRERAS ET AL.	
	Examiner	Art Unit	
	Kagnew H. Gebreyesus	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *28-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/8/04 & 4/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse dated June 7, 2006 to the Office Action sent on May 02, 2006 is acknowledged. Applicants provisionally elected the subject matter of Group 1, Claims 1-27. Applicants further elected Pichia pastoris as the species of the methylotrophic yeast strain and the "Trichoderma reesei" for a-1, 2-manosidase gene, "human" for GnT1, and "human" for Ga1T genes to be transformed in *Pichia pastoris*.

Priority

Priority is acknowledged for the filing date of November 14, 2003.

Information Disclosure Statement

The information disclosure statement filed on April 8, 2004 and April 18, 2005 for which a copy of the patent, publications were submitted in this application will be reviewed in full.

Oath/Declaration

Applicant has not given a post office address anywhere in the application papers as required by 37 CFR 1.33(a), which was in effect at the time of filing of the oath or declaration. A statement over applicant's signature providing a complete post office address is required. While the first three inventors indicate that the post office address is the same as the residence address, the forth inventor does not indicate the post office address.

Response to traversal:

Applicant's argument regarding rejoining the invention in Group I and Group II have been carefully considered. The claims in Group I are drawn to a product (a genetically engineered methylotrophic yeast strain) and the claims in Groups II are drawn to the process of using said product. The examiner had required restriction between product and process claims. Given that applicant have elected claims directed to the products, where a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Group I is drawn to a product (namely the recombinant methylotrophic yeast) that is structurally and functionally unrelated to the product of Group III (namely a glycoprotein with a specific structure). Considering the broadest interpretation, the claims in Group III do not require the use of the specific recombinant yeast. In addition the search and examination of the product in Groups I and the product in Group III in one patent application would result in undue burden, since the searches for the two groups are not co-extensive, since the searches are in different classifications, and involve different field of search. Each of the inventions requires a separate patent and non-patent literature search requiring a different text search for each group and thus co examination of the inventions in group I and group III would be a serious burden on the examiner.

As stated in the previous Office Action, inventions in group I are unrelated to inventions in group IV. The invention of Group IV is drawn to a vector comprising a single gene. The invention of IV is drawn to a vector (polynucleotide sequence) comprising a single gene encoding a GalT which when broadly interpreted is unrelated to the genetically engineered methylotrophic yeast strain that produces a glycoprotein having a mammalian-like N-glycan structure. Thus the invention of Group IV which is drawn to a nucleic acid sequence while the

invention of Group I is drawn to a recombinant organism which is a patentably unrelated product. In addition the search and examination of Groups I and IV in one patent application are not co-extensive and will would result in undue burden, since the searches are in different classifications, and involve different field of search. Each of the of the inventions requires a separate patent and non-patent literature search requiring a different text search for each group and thus co examination of the inventions in group I and group IV would be a serious burden on the examiner.

Furthermore applicants argue:

"... Applicants further submit that the interdependence of Groups I-V is confirmed -- indeed, it is mandated-- by virtue of the fact that 35 U.S.C. § 112 compels disclosure of all aspects of the invention in the one application which applicants have filed..."

However when examining claims in an invention, the broadest interpretation must be considered. Under these conditions the claims in Group V can have separate utilities as stated in the previous Office Action, thus are patentably independent.

The argument regarding the origin of the enzyme and the particular host has been considered and found persuasive. The requirement for an election of species with regard to the origin of the enzymes required in the process of producing a glycoprotein and the particular cell used as a host is hereby withdrawn.

While the search necessary for examination of the various Groups overlap the searches are not co-extensive therefore the requirement is still deemed proper and is therefore made FINAL.

Status of claims

Claims 1-38 are pending. Claims 28-38 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected groups, there being no allowable or linking claims. Claims 1-27 are present for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-4 are rejected because of the term "genetically engineered yeast strain" which does not define the genetic modification required to produce the strain(s). The specification does not define this term in any specific manner. Thus the metes and bounds of this term are not clear. The modification required to produce the genetically engineered yeast strain can be done in various ways. Claims 1-4 are indefinite since the modifications required to produce the specific genetically engineered strain are not clearly defined. For examination purposes the term will be understood as a strain wherein any man-made recombinant modification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims (1-4, 6, 27) are directed to a genetically engineered yeast strains which produce a genus of glycoproteins comprising mammalian like N-glycan structure wherein the mammalian-like N-glycan contains five or fewer mannose residues and at least one N-acetylglucosamine residue which is linked to a mannose residue and a terminal galactose residue. The specification teaches the structure of only a single representative species of a genetically engineered yeast strain namely *Pichia pastoris* can produce a glycoprotein comprising a specific mammalian-like-N-glycan structure, such as $GalGlcNAcMan_5GlcNAc_2$. The specification does not describe a genetically engineered yeast strain that can produce a genus of glycoproteins comprising mammalian like N-glycan structure wherein the mammalian-like N-glycan contains five or fewer mannose residues and at least one N-acetylglucosamine residue which is linked to a mannose residue and a terminal galactose residue. The specification does not describe the genetic modifications required to produce the specific genetically engineered strain in the presence of the endogenous α-1, 6-mannosytransferase (OCH1) gene or in the absence of enzymes required to modify the N-glycan structure of the glycoprotein produced (claims 1-4, 6 and 27). In addition the specification does not describe a strain that can produce a mammalian-like N-glycan which

contains four, three, or fewer mannose residues linked to one or more N-acetylglucosamine residue further linked to a mannose residue and a terminal galactose residue in the presence or absence of the endogenous OCH1 gene.

Given this lack of sufficient description of a genetically engineered yeast strain(s) wherein said strain(s) produce a genus of glycoproteins in the presence or absence of the endogenous OCH1 gene or the presence or absence of exogenously added (transformed genes) genes required to produce said glycoproteins comprising mammalian like N-glycan structure wherein the mammalian-like N-glycan contains five or fewer mannose residues and at least one N-acetylglucosamine residue which is linked to a mannose residue and a terminal galactose residue as encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

The court of appeals for the Federal Circute has held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as structure, formula [or] chemical name, 'of the claimed subject matter sufficient to distinguish it from other material. " For claims drawn to a genus, MPEP § 2163 states the written description required for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by a disclosure of relevant identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a

sufficient variety of species to reflect the variation within the genus. In this case, the specification discloses a single representative species of the genus of claimed mammalian-like-N-glycan structure, namely ($GalGlcNAcMan_5GlcNAc_2$).

The specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of being an engineered strain which produces a mammalian-like N-glycan which contains five or fewer mannose residues and at least one N-acetylglucosamine residue which is linked to a mannose residue and a terminal galactose residue in the presence of the OCH1 gene as encompassed in claims 1, 3-5, 7-27.

While MPEP § 2163 acknowledges that in certain situations "one species adequately supports a genus", it also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus." In the instant case the recited genus of yeast strains that produce a genus of glycoproteins that encompass species widely variant with respect to their structures, which include glycoproteins comprising a mammalian-like N-glycan which contain five or fewer mannose residues and one or more N-acetylglucosamine residue which is linked to a mannose residue and a terminal galactose residue.

As such, the disclosure of the single species of modified yeast strain glycoprotein is insufficient to be representative of the attributes and features of all species encompassed by the claimed genus of yeast strain. Given this lack of description of representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1- 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a genetically engineered methylotrophic *Pichia pastoris* yeast stain wherein said strain has a disruption of the α-1, 6-mannosytransferase gene (OCH1) and is transformed with an α-1, 2-mannosidase, an β-1,2-N-acetylglucosaminyltransferase I, and β-1,4-galactosyltransferase which enables the production of a glycoprotein comprising a specific mammalian-like-N-glycan structure, namely ($GalGlcNAcMan_5GlcNAc_2$) does not enable for any methylotrophic yeast strain genetically engineered to produce any mammalian N-glycan structure wherein the mammalian N-glycan structure contain five or fewer mannose residues and at least one N-acetylglucosamine residue which is linked to a mannose residue and a terminal galactose residue and wherein said strain dhas any genetic modification including the mutation of any endogenous genes of said yeast and/or the introduction of any heterologous gene.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized ln re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988). The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass a genetically engineered methylotrophic yeast stain that can produce a genus of glycoproteins having a mammalian N-glycan structure

wherein the mammalian N-glycan structure contains one to five mannose residues and one or more N-acetylglucosamine residue which is linked to a mannose residue and a terminal galactose residue in the presence of the endogenous OCH1 gene which adds mannose residues to glycoproteins and/or the absence of genes expressing enzymes with an α-1, 2-mannosidase, an N-acetylglucosaminyltransferase I, a β-galactosyltransferase activities.

The specification provides guidance and examples for a genetically engineered methylotrophic yeast stain, *Pichia pastoris* wherein the OCH1 gene is disrupted thus preventing high mannosylation and which produces a glycoprotein comprising a specific mammalian-like-N-glycan structure, namely ($GalGlcNAcMan_5GlcNAc_2$) as seen in fig. 1. However, the specification does not teach genetic modifications required to produce the specific genetically engineered strain that produces a mammalian-like-N-glycan structure, namely ($GalGlcNAcMan_5GlcNAc_2$) in the presence of the endogenous OCH1 gene and the presence or absence of enzymes required to modify the N-glycan structure of the glycoprotein produced . In addition the specification is not enabled for a strain that can produce a mammalian-like N-glycan which contains four, three, or fewer mannose residues linked to one or more N-acetylglucosamine residue further linked to a mannose residue and a terminal galactose residue while said yeast strain does not express enzymes required to modify the glycoprotein produced in the yeast strain and/or wherein the strain comprises an endogenous OCH1 gene.

Given that the OCH1 gene hypermannosylates glycoproteins produced in *Pichia pastoris* the skilled artisan would not have a reasonable expectation of success in producing a glycoproteins comprising mammalian like N-glycan structure as described above in the presence of the OCH1 gene and in the absence of endogenous or exogenously added genes that express

enzymes required to modify the glycoprotein to produce the glycoprotein comprising a specific mammalian-like-N-glycan structure wherein the mammalian-like N-glycan contains only five or fewer mannose residues linked to one or more N-acetylglucosamine residue further linked to a mannose residue and a terminal galactose residue. In addition the specification is not enabled for a methylotrophic yeast strain with a disruption of the OCH1 gene where the yeast does not have enzymes required for producing mammalian like N-glycan structure comprising a specific mammalian-like-N-glycan structure because yeast do not possess specific enzymes required (α-1, 2-mannosidase, an β-1,2-N-acetylglucosaminyltransferase I, a β-galactosyltransferase) in the specific trimming and addition of residues for the production of mammalian like N-glycan structures.

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed invention is enormous and undue. Such experimentation entails genetically modifying a yeast strain to enable said strain to produce a glycoprotein commensurate with a mammalian-like N-glycan structure by transforming said yeast strain with gene(s) that remove mannose residues and add residues necessary for said mammalian glycans or prevent attachment of mannose residues in view of designing because yeast cells have high mannose residues attached to mammalian like N-glycan structures wherein the mammalian N-glycan structure contains five or fewer mannose residues and one or more N-acetylglucosamine residue which is linked to a mannose residue with a terminal galactose residue and completely lack the enzymes necessary for producing mammalian like complex glycans,.

Thus, searching for a specific methylotrophic strain that produces a genus of glycoproteins and the specific genetic modification which will result in mammalian like N-glycan structures wherein the mammalian N-glycan structure contains five or fewer mannose residues and one or more N-acetylglucosamine residue which is linked to a mannose residue with a terminal galactose residue is well outside the realm of routine experimentation.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding all of the specific genetic modification required to produce the yeast strain having the specific characteristics. Without such guidance, the experimentation left to those skilled in the art is undue. Therefore one would not have a reasonable expectation of success in producing a genetically engineered yeast strain which produces glycoproteins comprising a mammalian like N-glycan structures wherein the mammalian N-glycan structure contains five or fewer mannose residues and one or more N-acetylglucosamine residue which is linked to a mannose residue with a terminal galactose residue wherein the endogenous OCH1 gene is functional in the absence or presence of enzymes with an α-1, 2-mannosidase, an N-acetylglucosaminyltransferase I, a β-galactosyltransferase activities because the OCH1 gene adds mannose residues to the glycoprotein and the results of the structure of the glycoprotein obtained will be unpredictable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Gerngross et al (US 7029872 B2). Gerngross et al disclose methods of producing recombinant glycoproteins comprising an N-glycan structure that comprises a $Man_5GlcNAc_2$ glycoform in a genetically engineered yeast strain, specifically *Pichia pastoris* lacking α-1, 6-mannosyltransferase activity (enzyme encoded by the OCH1 gene (see claim 8 and 13). Gerngross et al (page 17 column 1, line 30-58) disclose that *Pichia pastoris* can be modified by the expression of one or more human or animal glycosylation enzymes to obtain N-glycan similar or identical to human glycoforms (line 38-42). In addition Gerngross et al disclose examples of glycosylation enzymes such as enzymes that trim mannose residues from $Man_8GlcNac_2$ to yield $Man_5GlcNac_2$, enzymes such as N-acetylglucosamine transferase I (GnT1) to add an N-acetylglucosamine (GlcNac) residues to Man5GlcNac2 to produce GlcNacMan5GlcNac2 and additionally other genes that encode enzymes such as (GnT I-VI), mannosidaseII, fucosyltransferase, galactosyl transferase (GalT) or sialyltransferases (ST) in view of producing modified glycosylation pathways in eukaryotic cells in particular in *Pichia pastoris*. . In addition Gerngross et al in a preferred embodiment discloses the use of a *Pichia pastoris* strain having a disruption in the α-1, 6-mannosyltransferase (OCH1) gene to prevent hypermannosylation (see page 13 line 23-36 and claims 8, 13). Furthermore, Gerngross et al also disclose the use of genetic constructs encoding fusion of said glycosylation enzymes with targeting sequences for various cellular loci involved in glycosylation such as in the ER, cis golgi, medial golgi or trans-golgi. As an example Gerngross et al teach signal sequences that include retrieval signal peptides, e.g. the tetrapeptides HDEL or KDEL (anticipating claims 10-17). In

addition Gerngross et al teach examples of suitable promoters to drive the glycosylation enzymes such as AOX1, AOX2, DAS and the P40 promoters (anticipating claims 23-26). Thus the instant invention drawn to a genetically engineered methylotrophic *Pichia pastoris* yeast stain wherein said strain has a disruption of the α-1, 6-mannosytransferase gene (OCH1) and which produces glycoproteins comprising a mammalian like N-glycan structures wherein the mammalian N-glycan structure contains five or fewer mannose residues and one or more N-acetylglucosamine residues linked to a mannose residue and to a terminal galactose residue is anticipated by Gerngross et al.

Relevant literature:

US PAT 6,803,225 B2. Contreras et al. Protein glycosylation modifications in *Pichia pastoris*.

Hamilton et al. Production of Complex Human Glycoproteins in Yeast. August 2003. Science Vol. 301, p1244-1246.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H. Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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